911 KAR 1:085. Early Hearing Detection and Intervention Program.

RELATES TO: KRS 13B.050, 194A.030(5), 200.460-200.499, 211.645(5), 211.647, 213.046(16), 216.2970, 334A

STATUTORY AUTHORITY: KRS 194A.030(5), 194A.050(1), 211.647(3), 216.2970(1)

NECESSITY, FUNCTION, AND CONFORMITY: KRS 194A.050(1) requires the secretary of the Cabinet for Health and Family Services to promulgate administrative regulations necessary to operate the programs and fulfill the responsibilities vested in the cabinet, to implement programs mandated by federal law, or to qualify for federal funds. KRS 211.647(3) requires the Commission for Children with Special Health Care Needs to identify and refer for treatment infants at risk for hearing loss and establish standards for infant audiological assessment and diagnostic centers. KRS 216.2970(1) requires the commission to promulgate administrative regulations establishing approved methods for auditory screening for all infants born in hospitals offering obstetric services and alternative birthing centers with at least forty (40) births per year. This administrative regulation establishes standards, eligibility criteria, application processes, reporting requirements, and appeal rights for entities seeking designation as approved infant audiological assessment and diagnostic centers, and identifies approved methods for auditory screening for newborn infants in hospitals and alternative birthing centers.

Section 1. Definitions. (1) "AAA Guidelines" means the "Audiologic Guidelines for the Assessment of Infants and Young Children" published by the American Academy of Audiology.

- (2) "ASHA Guidelines" means the "Guidelines for the Audiologic Assessment of Children From Birth to 5 Years of Age", published by the American Speech-Language-Hearing Association.
 - (3) "Audiologist" is defined by KRS 334A.020(5).
- (4) "Audiology extern" means a student engaged in the clinical experience component of an audiology doctoral degree program.
- (5) "Auditory brainstem response" or "ABR" means an objective electrophysiologic measurement of the brainstem's response to the ear when stimulated with a click sound or tone burst.
- (6) "Automated auditory brainstem response" or "AABR" means an automatic ABR resulting in a pass/refer outcome.
 - (7) "Commission" is defined by KRS 211.645(2).
- (8) "JCIH Guidelines" means the "Year 2007 Position Statement: Principles and Guidelines for Early Hearing Detection and Intervention Programs", published by the Joint Committee on Infant Hearing.
- (9) "Otoacoustic emissions" means an objective physiological test method for measuring responses elicited directly from the cochlea.

Section 2. Eligibility Criteria for Centers. (1) In order to be eligible for designation as a Level 1 infant audiological assessment and diagnostic center, an entity located in Kentucky shall:

- (a) Employ at least one (1) audiologist who:
- 1. Is currently licensed pursuant to KRS Chapter 334A;
- 2. Has experience testing children in the age range newborn to three (3) years; and
- 3.a. Performs all evaluations; or
- b. Directly supervises audiology externs performing evaluations;
- (b) Possess the capacity to complete the following tests:
- 1. Otoscopic examination;
- 2. Tympanometry;

- 3. Ipsilateral acoustic reflex measurement:
- 4. Contralateral acoustic reflex measurement;
- 5. Ear-specific behavioral observation audiometry;
- 6. Speech awareness threshold;
- 7. Speech recognition or reception threshold;
- 8. Play audiometry; and
- 9. Either:
- a. Otoacoustic emissions with diagnostic or screening capabilities; or
- b. ABR screening;
- (c) Annually calibrate all measuring and testing equipment; and
- (d) Submit a complete application and assurance packet in accordance with Section 3 of this administrative regulation.
- (2) In order to be eligible for designation as a Level 2 infant audiological assessment and diagnostic center, an entity located in Kentucky shall:
 - (a) Meet the requirements specified in subsection (1) of this section; and
 - (b) Possess the capacity to complete:
 - 1. Otoacoustic emissions with diagnostic or screening capabilities;
 - 2. Frequency-specific ABR;
 - 3. Bone conduction ABR; and
 - 4. Real ear measures.

Section 3. Application Process. (1) An entity seeking designation as an infant audiological assessment and diagnostic center shall submit to the commission a completed application packet containing:

- (a) Completed and signed form CCSHCN-E106, Potential Infant Audiological Assessment and Diagnostic Center Questionnaire;
 - (b) Copies of current professional licenses for audiologists performing evaluations;
 - (c) Copies of current calibration certificates for audiological testing equipment; and
- (d) Copies of policies and procedures for tests and measures requested on the CCSHCN-E106, Potential Infant Audiological Assessment and Diagnostic Center Questionnaire.
- (2) The commission shall review an entity's application within thirty (30) calendar days of receiving a complete packet submitted in accordance with subsection (1) of this section.
- (3) Upon review of an entity's application packet, the commission's executive director or designee shall approve the entity as a Level 1 Infant Audiological Assessment and Diagnostic Center if:
- (a) The entity meets the requirements specified in Section 2(1) of this administrative regulation; and
- (b) The commission determines that the entity's policies and procedures conform to best practice standards as described in JCIH Guidelines and:
 - 1. AAA Guidelines; or
 - 2. ASHA Guidelines.
- (4) Upon review of an entity's application packet, the commission's executive director or designee shall approve the entity as a Level 2 Infant Audiological Assessment and Diagnostic Center if:
- (a) The entity meets the requirements specified in Section 2(2) of this administrative regulation; and
- (b) The commission determines that the entity's policies and procedures conform to best practice standards as described in JCIH Guidelines and:
 - 1. AAA Guidelines; or

- 2. ASHA Guidelines.
- (5) If the commission's executive director or designee determines that the entity does not meet the requirements specified in Section 2 of this administrative regulation, the Commission shall:
 - (a) Advise the entity and request clarifying information; or
- (b) Deny the designation as an Infant Audiological Assessment and Diagnostic Center and notify the entity of appeal rights pursuant to Section 8 of this administrative regulation.
- (6) Approvals shall expire on December 31 of odd-numbered years. All entities seeking continued approval shall re-apply by December 1 of that year in accordance with this section.

Section 4. Publication of Approved List. (1) In accordance with KRS 211.647, the Commission shall maintain a current listing of all approved Infant Audiological Assessment and Diagnostic Centers, with contact information.

- (2) The Commission shall make the listing public through the following methods:
- (a) Posting on its agency Web site, http://chfs.ky.gov/ccshcn;
- (b) Providing to the Cabinet for Health and Family Services, Office of Administrative and Technology Services, for inclusion on the KY-CHILD electronic information system used by birthing hospitals and centers;
 - (c) Enclosing as an attachment to correspondence with parents; and
 - (d) Mailing a listing to birthing hospitals and centers upon request.

Section 5. Removal from Approved List and Updates Required. (1) The commission shall remove an entity from the approved list and notify the entity of the removal if the entity requests removal.

- (2) If the commission receives a complaint that an entity no longer meets the requirements of Section 2 of this administrative regulation, the commission shall:
 - (a) Advise the entity of the complaint;
 - (b) Request clarifying information from the entity;
 - (c) Review any information received; and
- (d) Determine whether the entity meets the eligibility requirements of Section 2 of this administrative regulation.
- (3) If the commission determines that the entity no longer meets the eligibility requirements, the commission shall:
- (a) Notify the entity of appeal rights pursuant to Section 8 of this administrative regulation; and
 - (b) Remove the entity from the approved list.
- (4) Following approval, an Infant Audiological Assessment and Diagnostic Center shall provide documentation via form CCSHCN-E107, Infant Audiological Assessment and Diagnostic Center Program Modification, if the following changes in circumstances occur:
 - (a) Employment or termination of employment of an audiologist;
 - (b) Change in licensure status of an audiologist;
 - (c) Relocation of agency or addition of a location; or
- (d) Modification to policy or procedure with regard to evaluations described in Section 2 of this administrative regulation.

Section 6. Reporting Requirements. (1) Upon completion of diagnostic testing of an infant or child aged birth to three (3) years described in KRS 211.647(5), an approved Infant Audiological Assessment and Diagnostic Center shall report to the commission:

(a) Identifying and demographic information;

- (b) Results of the follow-up audiological evaluation; and
- (c) Documentation of the referral required by KRS 211.647(5).
- (2) An approved Infant Audiological Assessment and Diagnostic Center shall submit information specified in subsection (1) of this section electronically via the KY-CHILD electronic information system within seven (7) calendar days of evaluation.
- (3) Scheduled appointments which are not kept by families shall be marked in the KY-CHILD electronic information system as no-show within four (4) calendar days if not rescheduled.
- Section 7. Resource and Informational Materials. The commission shall make available to families of all newborns and children ages birth to three (3) years identified as having permanent hearing loss information provided by the Kentucky Commission on the Deaf and Hard of Hearing.
- Section 8. Appeal Rights. An entity denied designation as an Infant Audiological Assessment and Diagnostic Center or which has been removed from the approved list may request an administrative hearing in accordance with KRS 13B.050.
- Section 9. Approved Methods of Auditory Screening for Newborn Infants and Children Ages Birth to Three (3) Years. (1) Auditory screenings pursuant to KRS 216.2970(1) shall include at least one (1) of the following physiological tests:
 - (a) AABR; or
 - (b) Otoacoustic emissions.
 - (2) Auditory screening reports shall:
 - (a) Document the results of physiological tests conducted;
 - (b) Document the presence of any risk factors pursuant to KRS 211.645(5); and
 - (c) Be submitted via the KY-CHILD electronic information system.

Section 10. Incorporation by Reference. (1) The following material is incorporated by reference:

- (a) "Audiologic Guidelines for the Assessment of Infants and Young Children", American Academy of Audiology, August 2012;
- (b) "CCSHCN-E106, Potential Infant Audiological Assessment and Diagnostic Center Questionnaire", 2009;
- (c) "CCSHCN-E107, Infant Audiological Assessment and Diagnostic Center Program Modification", 2009;
- (d) "Guidelines for the Audiologic Assessment of Children From Birth to 5 Years of Age", 2004 American Speech-Language-Hearing Association; and
- (e) "Year 2007 Position Statement: Principles and Guidelines for Early Hearing Detection and Intervention Programs", 2007 Joint Committee on Infant Hearing.
- (2) This material may be inspected, copied, or obtained, subject to applicable copyright law, at the Commission for Children with Special Health Care Needs, 310 Whittington Parkway, Suite 200, Louisville, Kentucky 40222, Monday through Friday, 8 a.m. to 4:30 p.m. (27 Ky.R. 2013; Am. 2469; eff. 3-6-2001; recodified from 902 KAR 4:085, 8-10-2001; 36 Ky.R. 698; 1228; eff. 1-4-2010; 41 Ky.R. 1226; 1658; eff. 2-5-2015.)